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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/761,185	01/20/2004	Austin W. Mutchler	DEP5031	2594
<div>27777 7590 01/08/2008</div> <div>PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003</div>				
			<div>EXAMINER</div> <div>CUMBERLEDGE, JERRY L</div>	
			<div>ART UNIT</div> <div>3733</div>	<div>PAPER NUMBER</div>
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/761,185

Applicant(s)

MUTCHLER, AUSTIN W.

Examiner

Jerry Cumberledge

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 7-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 7-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 September 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 8, 10-16, 18, 20-27, 29, 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ackeret et al. (US Pat. 6,319,253 B1) in view of Sohngen (US Pub. 2003/0195515 A1).

Ackeret et al. disclose an intramedullary nail (Fig. 1, ref. 1a) (abstract) for use with a first fastener and a second fastener for use in orthopaedic surgery, said nail comprising a body (Fig. 1, ref. 1a) defining a longitudinal axis thereof, the body having a continuous edge (Fig. 1a, edge near refs. 4 and 5) defining an aperture (Fig. 1a, refs. 4 and 5) therethrough, the continuous edge having opposed straight parts (Fig. 1a, near ref. 6) and curved parts (Fig. 1a, refs. 4 and 5), the aperture having a first portion defined by the opposed straight parts of the continuous edge (Fig. 1) for cooperation with the first fastener to provide dynamic fixation and having two spaced cylindrical end portions (Fig. 1a, end portions near refs. 4 and 5) defined by the curved parts of the continuous edge for cooperation with the second fastener to provide static fixation (Fig. 1a), the first portion of the aperture lying between the cylindrical portions of the aperture (Fig. 1a), the cylindrical portions of the aperture having widths greater than the distance between the opposed straight parts of the continuous edge defining the first portion of

the aperture (Fig. 1a). The opposed straight parts of the continuous edge define a rectangular central section (Fig. 1a). The cylindrical end sections are adapted to matingly fit with the first fastener (Fig. 2a). The cylindrical end sections are adapted to one of slidable fit and threadable fit with the first fastener (Fig. 2a). The aperture is adapted to provide for a slidable fit of the first fastener with said body along the longitudinal axis of said body (Fig. 2a). The aperture defines a slot axis thereof, the slot axis being perpendicular to the longitudinal axis of said body (Fig. 1a).

Ackeret et al. disclose a kit for use in orthopaedic surgery, the kit comprising: a first fastener (Fig. 2a, ref. 11) comprising a shank (Fig. 2a) having maximum outer diameter; a second fastener (Fig. 2a, ref. 10) comprising a shank having a maximum outer diameter (Fig. 2a); and an intramedullary nail (Fig. 1a, ref. 1) (abstract) comprising a body (Fig. 1, ref. 1) having two ends and an edge (Fig. 1a, edge near refs. 4 and 5) defining an aperture (Fig. 1a, refs. 4 and 5), therethrough the edge being spaced from the two ends (Fig. 1a) and including first substantially parallel parts (Fig. 1a, near ref. 6) defining a first portion of the aperture (Fig. 1a) sized and shaped to cooperate with said first fastener to provide dynamic fixation and having a second curved part (Fig. 1a, portion near ref. 4) extending from and connected to said first substantially parallel parts (Fig. 1a) defining a curved portion of the aperture (Fig. 1a) sized and shaped to cooperate with said second fastener to provide one of static fixation and dynamic fixation, the second curved portion of the aperture having a width greater than the distance between the first substantially parallel parts of the edge defining the first portion of the aperture (Fig. 1a); and wherein the maximum outer diameter of the shank

of the second fastener is greater than the distance between the first substantially parallel parts of the edge defining the first portion of the aperture (Fig. 2b). The first substantially parallel edges of the aperture define a rectangular central section (Fig. 1a) and the second curved portion of the aperture defines a cylindrical end section adjoining the rectangular central section (Fig. 1a). The cylindrical end section is adapted to matingly fit with the second fastener. The cylindrical end section is adapted to one of slidable fit and threadable fit with the fastener. The body has a longitudinal axis extending through at least one of the ends of the body and wherein the aperture is adapted to provide for a slidable fit of the first fastener with said body along the longitudinal axis of said body. The aperture further includes a second cylindrical end section (Fig. 1a, end near ref. 5) opposed to the first mentioned cylindrical end section. The aperture defines a slot axis thereof, the slot axis being perpendicular to the longitudinal axis of said body (Fig. 1a).

Ackeret et al. disclose a method for use in orthopaedic surgery comprising: providing an orthopaedic surgery kit including a first fastener (Fig. 2a, ref. 11) comprising a shank (Fig. 2a) having a maximum outer diameter (Fig. 2a), a second fastener (Fig. 2a, ref. 10) comprising a shank (Fig. 2a) having a maximum outer diameter greater than the maximum outer diameter of the first fastener (Fig. 2a), and an intramedullary nail (Fig. 2b, ref. 1) having a body defining a longitudinal axis thereof (Fig. 2a), the body having an edge (Fig. 1a, edge near refs. 4 and 5) defining an aperture (Fig. 1a, refs. 4 and 5) therethrough, the aperture having a first portion (Fig. 1a) for cooperation with the first fastener to provide dynamic fixation and having a

second portion (Fig. 1a) extending from and connected to the first portion for cooperation with the second fastener to provide static fixation, the edge continuing around and defining both the first and second portions of the aperture (Fig. 1a); cutting an incision in the patient (since this must occur prior to inserting the intramedullary nail in the body); preparing a bone cavity (since the intramedullary canal must have a cavity in which it is placed within the body); inserting the nail into the cavity; choosing one of static fixation (column 1, lines 57-67, since the device is to be statically placed within the bone, e.g. "contribute to prevent longitudinal displacement of the nail") and dynamic fixation for the surgery; selecting one of the first fastener and the second fastener based on the choice of one of static fixation (Fig. 2a) and dynamic fixation for the surgery; and securing the chosen one of the first fastener and the second fastener into the nail wherein the maximum outer diameter of the second fastener is greater than the width of the first portion of the aperture (Fig. 2a), and wherein the first fastener is secured in the first portion of the aperture if dynamic fixation is chosen and the second fastener is secured in the second portion of the aperture if static fixation is chosen (Fig. 2a, 2b).

Ackeret et al. disclose a kit for use in orthopaedic surgery, the kit comprising a first fastener (Fig. 3a, ref. 11) including a shank (Fig. 3a) having a maximum outer diameter (Fig. 3a), a second fastener (Fig. 3a, ref. 11) including a shank (Fig. 3a, ref. 11) having a maximum outer diameter (Fig. 3a), a third fastener (Fig. 3a, ref. 11) including a shank (Fig. 3a) having a maximum outer diameter (Fig. 3a), and an intramedullary nail (Fig. 1a, ref. 1) comprising: a body (Fig. 1a, ref. 1) having a first end, a second end and an edge (Fig. 1a, edge near refs. 4 and 5) defining an aperture (Fig.

1a, refs. 4 and 5) therethrough, the edge defining the aperture being spaced from the first and second ends and having a curved part (Fig. 1, near ref. 4) and opposed straight parts (Fig. 1a, near ref. 6), the curved part of the edge extending for more than 180 degrees (Fig. 1a), the aperture being substantially longer in the longitudinal axis than in transverse axis (Fig. 1a), the aperture defining an enlarged portion thereof along the curved edge (Fig. 1a), the enlarged portion having a diameter (Fig. 1a), the aperture having a constricted portion (Fig. 1a, near ref. 6) adjacent and connected to the enlarged portion (Fig. 1a) defined by the two opposing straight parts of the edge (Fig. 1a), the diameter of the enlarged portion being greater than the distance between the two opposing parts of the edge defining the constricted portion of the aperture (Fig. 1a); wherein the maximum outer diameter of the shank of the second fastener is great enough to allow for static fixation when the second fastener is placed in the enlarged portion of the aperture; wherein the first fastener and the constricted portion of the aperture are sized to allow for dynamic fixation with a degree of relative movement allowable between bone parts and the third fastener and the enlarged portion of the aperture are sized to allow for dynamic fixation with a lesser degree of relative movement allowable between bone parts. The aperture has a rectangular central section (Fig. 1a); and wherein the enlarged portion is in the form of a generally cylindrical section and is positioned adjacent an end of the rectangular central section of the aperture (Fig. 1a). The cylindrical section of said body is adapted to matingly fit with said second fastener. The cylindrical section is adapted to slidably fit with said first and third fasteners and threadably fit with said second fastener. The body has a longitudinal

axis (Fig. 1a) extending through at least one of the first and second ends and wherein the aperture is adapted to provide for a slidable fit of said fastener with said body along the longitudinal axis of said body. The aperture further includes a second enlarged cylindrical section opposed to the first mentioned cylindrical section (Fig. 1a, near ref. 5). The enlarged portion is adjacent an end of the aperture (Fig. 1a).

Ackeret et al. disclose the claimed invention except for the aperture being symmetrical about a longitudinal axis extending between the cylindrical portions and between the straight parts of the edge; the aperture being symmetrical about a longitudinal axis extending from the second curved portion and between the substantially parallel parts; the aperture being symmetrical about an axis through the enlarged portion and constricted portion. Ackeret et al. does disclose that the shape of the slot can be modified (column 3, lines 20-25).

Sohngen discloses an intramedullary nail that comprises an aperture that is symmetrical about a longitudinal axis extending between cylindrical portions and between straight parts of an edge (Fig. 1, ref. 54). This symmetry allows for a more even distribution of forces throughout the nail once it has been emplaced within the bone.

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the bore of Ackeret et al. as being symmetrical, since this would allow for a more even distribution of forces throughout the nail once it has been emplaced within the bone.

With regard to claim 21, Ackeret et al. disclose the claimed invention except for the maximum outer diameter of the first fastener being less than the distance between the straight parallel parts of the edge.

Sohngen discloses an intramedullary nail that comprises a slot that comprises straight parallel parts and a fastener that has a maximum shaft diameter that is less than the distance between the straight parallel parts of the edge (Fig. 8, ref. 56). This allows the slot and the fastener to provide dynamic fixation of an injured bone, since the fastener can slide within the slot (paragraph 0045).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the device of Ackeret et al. with a slot and fastener as taught by Sohngen, in order to allow the device of Ackeret et al. to provide dynamic fixation of an injured bone (paragraph 0045).

With regard to claims 8, 11-16, 18, 20, 22-27, 29, 31 and 32, Ackeret et al. disclose the claimed invention except for the intramedullary nail further comprising a resorbable component received within one of the cylindrical portions of the aperture and engaging the parts of the edge defining the cylindrical portion of the aperture; and the maximum outer diameter of the shank of the first fastener being less than the distance between the first substantially parallel parts of the edge defining the first portion of the aperture

Sohngen discloses an intramedullary nail (Fig. 2) that comprises a resorbable component (Fig. 2, ref. 50)(paragraph 0045) that is found within a cylindrical portion of

an aperture (Fig. 2, aperture near ref. 56). The maximum outer diameter of the shank (Fig. 14, shank of ref. 32) of the first fastener is less than the distance between the first substantially parallel parts (Fig. 8, parallel portions of ref. 56) of the edge defining the first portion (since this must be the case in order to allow dynamization to occur). The aperture, shank and the resorbable material are used for dynamization, in order to decrease the load carried by the fasteners and nail member and transfer the load to the fracture as the fracture heals (paragraph 0045).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have utilized a resorbable component as taught by Sohngen with the intramedullary nail of Ackeret et al., in order to make the implant dynamic, which will work to decrease the load carried by the fasteners and nail member and transfer the load to the fracture as the fracture heals (paragraph 0045).

With regard to claim 32, Ackeret et al. in view of Sohngen disclose the claimed invention except for the third fastener. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have constructed the kit of Ackeret et al. with a third fastener, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ackeret et al. (US Pat. 6,319,253 B1) in view of Emilio et al. (US Pat. 5,814,047).

Ackeret et al. disclose the claimed invention except for the body adjacent the first mentioned cylindrical end defines internal threads therein; and wherein said body adjacent the second cylindrical end defines internal threads therein. The body comprises internal threads formed in the body adjacent the aperture; and wherein said resorbable component comprises external threads formed thereon for cooperation with internal threads of said body.

Emilio et al. disclose the body adjacent the first mentioned cylindrical end (Fig. 12, 130) defining internal threads therein (Fig. 12, 131) and the body adjacent the second cylindrical end (Fig. 12, 140) defining internal threads therein (Fig. 12, 141) (see also Fig. 9), for engagement and guiding of screws (column 5, lines 19-24).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the intramedullary nail of Ackeret et al. with the body adjacent the first mentioned cylindrical end defining internal threads therein and the body adjacent the second cylindrical end defining internal threads therein, for engagement and guiding of screws (column 5, lines 19-24).

Claims 9, 17, 19, 28 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ackeret et al. (US Pat. 6,319,253 B1) in view of Sohngen (US Pub. 2003/0195515 A1) in view of Emilio et al. (US Pat. 5,814,047).

Ackeret et al. in view of Sohngen disclose the claimed invention except for the resorbable component comprising external threads formed thereon.

Emilio et al disclose the body adjacent the first mentioned cylindrical end (Fig. 12, 130) defining threads therein (Fig. 12, 131) and the body adjacent the second cylindrical end (Fig. 12, 140) defining internal threads therein (Fig. 12, 141) (see also Fig. 9), for engagement and guiding of screws (column 5, lines 19-24).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the intramedullary nail of Ackert et al. in view of Sohngen with threads in the in the body (e.g. the resorbable component) adjacent the first and second cylindrical ends, for engagement and guiding of screws (column 5, lines 19-24).

Response to Arguments

Applicant's arguments with respect to claims 1-5 and 7-32 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Cumberledge whose telephone number is (571) 272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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